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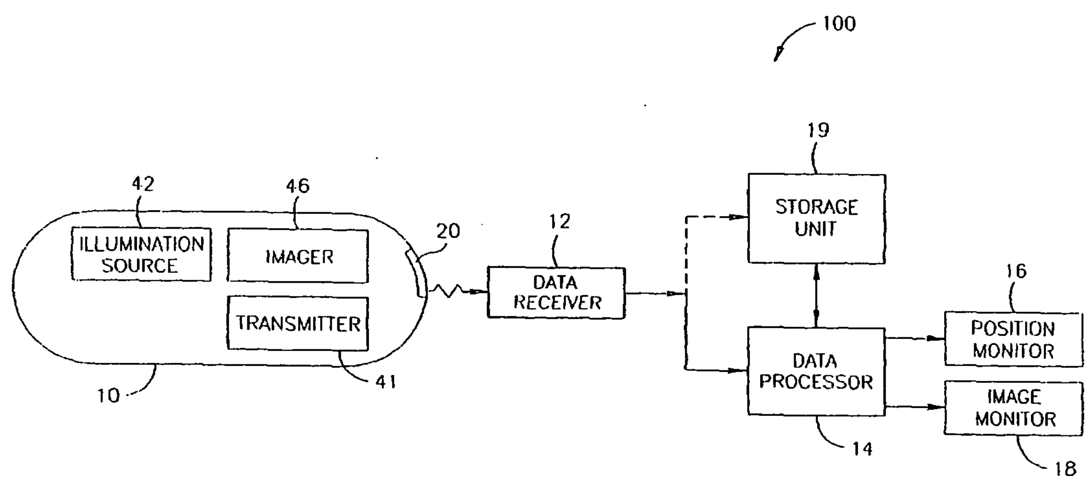
(54) **Title:** SYSTEM AND METHOD FOR IN VIVO SENSING



(57) **Abstract:** An apparatus, system and method that enables sensing and/or measuring environmental conditions in an in vivo environment. An environment sensitive material, such as a temperature sensitive color changing material, may be placed within or without of an in-vivo imaging device. The environment sensitive material may change in response to environmental changes, such as temperature changes, pH level changes, pressure changes etc., and the in-vivo imaging device may acquire these responses. These responses may be acquired by an imager, in the form of images that indicate the color status of the environment sensitive material for each data frame sent from the in-vivo imaging device to a data receiving unit and/or data processor. The data may be processed and analyzed etc. by a data processor, and output by an output device.

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SYSTEM AND METHOD FOR IN VIVO SENSING

FIELD OF THE INVENTION

[001] The present invention relates to systems, methods, and apparatuses useful in sensing and/or measuring in vivo conditions. Specifically, embodiments of the present invention relate to at least one apparatus, system, and method that provide for sensing or measuring of temperature, pressure and pH levels etc. in in-vivo environments.

BACKGROUND OF THE INVENTION

[002] In many circumstances it may be important to measure in vivo conditions, such as temperature, pressure or pH levels etc. inside a body. Such circumstances may occur, for example, during medical diagnostics and/or treatment of internal parts of a body.

[003] In living bodies, parameters such as temperature, pressure and/or pH changes etc. can be indicative of a pathology or abnormality etc. It may be important to measure in vivo parameters and optionally attain real time feedback as to the parameters. Furthermore, it may be important to be able to measure and optionally provide real time feedback for in vivo parameters that are typically difficult to access for conventional measuring mechanisms. For example, it is typically difficult to provide instrumentation that may access an area such as the gastrointestinal (GI) tract. Of course, other structures and areas of the body may require such sensing or measuring.

[004] It would be highly advantageous to have a measuring means that may reach places within the body that are usually difficult to reach, and provide in vivo data for environmental parameters, optionally providing real time feedback of this data.

SUMMARY OF THE INVENTION

[005] There is provided, in accordance with an embodiment of the present invention, an apparatus, system, and method for sensing an environment, such as inside a body

(in vivo). The apparatus, system, and method may utilize, for example, temperature and/or pH and/or pressure sensitive color-changing material etc. to indicate internal body environmental changes. In one embodiment, the material that may be used is thermotropic liquid crystal.

[006] According to some embodiments, an apparatus may include an ingestible device, such as a swallowable capsule, having color-changing material placed on an inner and/or outer surface. According to some embodiments of the present invention, there may be at least one light source for illuminating the color-changing material, and an imager capable of capturing images of the color-changing material. According to some embodiments of the present invention, environmental temperature (and/or pH and/or pressure etc.) and/or a change of environmental temperature (and/or pH and/or pressure etc.) may result in a color change of the environment sensitive color changing material. Samples of acquired data that indicate the color status of the environment sensitive color changing material may be transmitted, for example, to a data receiving unit, stored in a storage unit, processed by a processing unit and/or displayed by an output device, optionally in real time. The color change of the material may typically be determined according to the relation between each color and the measured environment parameter or value (temperature, pressure, pH, etc).

BRIEF DESCRIPTION OF THE DRAWINGS

[007] The principles and operation of the system, apparatus, and method according to embodiments of the present invention may be better understood with reference to the drawings, and the following description, it being understood that these drawings are given for illustrative purposes only and are not meant to be limiting, wherein:

[008] Fig. 1 is a schematic illustration of various components of a device and viewing system;

[009] Fig. 2 is a schematic illustration of a measuring sensitive element placed within an in-vivo device, according to some embodiments of the present invention;

[0010] Fig. 3 is a is a block diagram illustration of a work flow between various system components, according to some embodiments of the present invention;

[0011] Fig. 4 is a flowchart illustrating a method of measuring in vivo temperature changes, according to some embodiments of the present invention;

[0012] Fig. 5 is a calibration curve illustrating a relationship between hue values and temperature for a measurement material, according to some embodiments of the present invention;

[0013] Fig. 6 is a calibration curve illustrating a second relationship between hue values and temperature for a measurement material, according to some embodiments of the present invention.

[0014] It will be appreciated that for simplicity and clarity of illustration, elements shown in the figures have not necessarily been drawn to scale. For example, the dimensions of some of the elements may be exaggerated relative to other elements for clarity. Further, where considered appropriate, reference numerals may be repeated among the figures to indicate corresponding or analogous elements throughout the serial views.

DETAILED DESCRIPTION OF THE INVENTION

[0015] The following description is presented to enable one of ordinary skill in the art to make and use embodiments of the present invention as provided in the context of a particular application and its requirements. Various modifications to the described embodiments will be apparent to those with skill in the art, and the general principles defined herein may be applied to other embodiments. Therefore, the present invention is not intended to be limited to the particular embodiments shown and described, but is to be accorded the widest scope consistent with the principles and novel features herein disclosed. In other instances, well-known methods, procedures, and components have not been described in detail so as not to obscure the present invention.

[0016] Unless specifically stated otherwise, as apparent from the following discussions, it is appreciated that throughout the specification discussions utilizing terms such as “processing”, “computing”, “calculating”, “determining”, or the like, refer to the action and/or processes of a computer or computing system, or similar electronic computing device, that manipulate and/or transform data represented as

physical, such as electronic, quantities within the computing system's registers and/or memories into other data similarly represented as physical quantities within the computing system's memories, registers or other such information storage, transmission or display devices.

[0017] The platforms, processes and displays presented herein are not inherently related to any particular computer or other apparatus. Various general-purpose computing systems and networking equipment may be used with programs in accordance with the teachings herein, or it may prove convenient to construct a more specialized apparatus to perform the desired method. The desired structure for a variety of these systems will appear from the description below. In addition, embodiments of the present invention are not described with reference to any particular programming language. It will be appreciated that a variety of programming languages may be used to implement the teachings of the present invention as described herein.

[0018] In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be understood by those skilled in the art that embodiments of the present invention may be practiced without these specific details.

[0019] It will be appreciated that the term "environment" in the present invention relates to any space in which an in-vivo device may function, including, for example, within body lumen, cavity, organ, canal, wall etc. The phrase "environmental parameters" as used hereinafter may encompass, for example, temperature levels, pH levels, pressure levels, bacteria levels or any other relevant in vivo parameters that may be measured The phrase "in vivo" as used hereinafter may encompass any space within a living organism, such as inside a body of a living organism, including a human body, animal body, or any other suitable body.

[0020] It is noted that while the embodiments of the invention shown hereinbelow are typically adapted for imaging of the gastrointestinal (GI) tract, the devices and methods disclosed herein may be adapted for imaging other body cavities or spaces etc.

[0021] Specifically, embodiments of the present invention enable sensing or measuring of in vivo environmental parameters, and optionally enabling analysis and

display of these parameters or parameter changes. According to some embodiments of the present invention, measuring material or elements may be placed within or on an in-vivo device. Data attained by these elements may be transmitted to a data receiving unit and to a data processor and image monitor etc.

[0022] Reference is now made to **Fig. 1**, which is a schematic illustration of an in-vivo imaging device and system 100, according to some embodiments of the present invention. Such an embodiment may include, for example: a swallowable capsule 10, with an imager 46, transmitter 41, and environment sensing element 20; a data receiver unit 12 for receiving in-vivo imaging device data; a data processor 14; and displaying apparatuses such as 16 and 18. For example, a data receiver unit 12 may receive the data from the in-vivo imaging device 10, and may thereafter transfer the data to a data processor 14, and optionally a data storage unit 19. The data may be displayed on a position monitor 16 and/or an image monitor 18. While Fig.1 shows separate monitors, both an image and its position can be presented on a single monitor. Data receiver unit 12 may be separate from the processing unit 14 or combined with it. Data processor 14 may be, for example, a personal computer or workstation, and may include, for example, a processor memory etc. Data processor 14 may be configured for real time processing and/or for post processing to be viewed or otherwise displayed at a later date. Units 14, 16, 18 and 19 may be integrated into a single unit, or any combinations of the various units may be implemented. Of course, other suitable components may be used.

[0023] Detection of various environmental parameters, such as internal temperature, pressure and pH levels etc. may be enabled by determining, for example, the changes in color of parameter sensitive color-changing materials, such as temperature sensitive material. Other environment sensors or environmental parameter sensitive materials etc. may be used to determine alternative internal environmental changes. Reference is now made to **Fig. 2**, which is a schematic diagram of a color changing material 20 attached to an in-vivo imaging device 10. An example of a temperature sensitive color changing material is a thermotropic color changing liquid crystal material. An example of pH sensitive color changing material is litmus paper. Another example of pH sensitive color changing material is Liquid crystal material that may change color in response to pressure. Examples of pressure sensitive color changing materials are shear-sensitive liquid crystal coatings (SSLCC)

that when applied to planar surfaces may reveal (via color change) the nature of a shearing force. It is known that changes in applied shear stress magnitude may cause the liquid crystal molecular arrangement to change, thereby reorienting the scattered light spectrum in space. A fixed observer may thereby see color change in response to the altered shearing force. Such color changes may be continuous and reversible, with time response in the order of milliseconds. Another example of a pressure sensitive color changing material is a "Pressurex", a color changing irreversible material by Sensor Products Inc. (188 Rt. 10 Suite 307 East Hanover, NJ 07936-2108 USA).

[0024] The in-vivo device 10 may record or otherwise acquire images of the color changing material 20, using at least imager 46. Imager 46 may also image an in vivo site. The acquired images may be transmitted to a data receiving unit 12 and/or storage unit 19 and/or data processor 14. The data from the acquired images of the color changing material 20, for example, may be processed, analyzed and/or viewed etc. on, for example, a position monitor 16 and/or image monitor 18. The data may be presented as a number, as a graph, as a color chart or map, or in any other form. Optionally, the color-changing material 20 may be viewed while inside the body lumen so that any color change of the material may be detected, analyzed and/or presented to a viewer, typically a doctor, optionally in real time. The detection and/or analysis and/or display etc. of the acquired image data may include translation of the data into a corresponding change of the measured parameter. For example, the detection and display of an in vivo temperature change may be indicated by a corresponding change in color of the color changing material 20.

[0025] In addition to revealing pathological conditions of body lumen, some embodiments system 100 may provide information about the location of these pathologies, for example in the gastrointestinal tract (GI) tract. The information obtained by visual means, by viewing the color changing material 20 or information obtained by processing such color information, may be complemented and/or localized by providing information relating to alternative local (environmental) conditions, such as pH and/or pressure levels etc. in, for example, the GI tract or other body lumens, such as the reproductive tract etc. In this way an in-vivo imaging device may provide data for a frame that includes more than one environmental parameter, such as, for example, temperature and pH level in an environment etc. For example, by placing a plurality of different sensitive materials 20, a plurality of parameters may

be measured for each frame, and any combinations of parameters may be provided. Localization in a body lumen, such as the GI tract, may be determined, for example, as described in US patent number 5,604,531 and/or US application number 10/150,018, both assigned to the common assignee of the present application and which are hereby incorporated by reference. Examining local changes of parameters, such as temperature and pH for example, may provide additional information to, for example, a physician, for, for example, identification and localization of pathologies.

[0026] According to some embodiments of the present invention, the temperature sensitive material 20 may be connected to an in vivo device 10 or a part thereof, such as an in-vivo camera system. The in-vivo device 10 may be included on or within any suitable apparatus that may be introduced into the body to view the interior, such as an endoscope, a catheter, an ingestible capsule, and any other suitable imaging device. In-vivo imaging device may also be autonomous, such as in the case of an autonomous capsule. "Temperature-sensitive" in the context of the present invention may be defined as reactive to changes in temperature. This temperature change may include a range of temperatures or just a change from a reference temperature to another temperature. In other embodiments, device 10 may include pressure-sensitive, pH sensitive or alternative environmental parameter measuring color-changing materials. Thus, different properties within the environment of the body lumen can be measured in a similar manner to the one described for temperature hereinbelow. Other parameter measuring materials, which may not be color-changing, may be used for measuring in vivo environmental changes. For example, known pH and pressure sensors may be used for determining in vivo environmental changes.

[0027] As shown in Fig. 2, temperature-sensitive color-changing material 20 may be placed on the inside of device 10, the sensitive (color changing) portion facing inwards towards the device imager 46. By placing material 20 on the inside of device 10, many potential problems, such as complications associated with the biocompatibility and the resilience of material 20 in light of bodily fluids and pH changes etc., may be avoided. However, it should be apparent that color-changing material may also be placed on the outside of device 10. The attachment or placement of material 20 may be accomplished in a plurality of ways. For example, in one embodiment material 20 may be in the form of paint, and may be painted onto device 10. In another embodiment, material 20 may be attached onto device 10 with

adhesive. In another embodiment, material 20 may be sprayed onto device 10 as a coating. In other embodiments material 20 may be temperature adhered (welded), or adhered using pointwise binding or any other suitable means. The color changing material may alternatively be attached to a substrate (either transparent or non-transparent), and the substrate may be attached to, for example, the envelope of device 10. The color changing material 20 may be of other forms and may be adhered to the in-vivo imaging device in other ways.

[0028] According to some embodiments of the present invention, light from at least one light source 43 may be directed towards and/or through temperature-sensitive color-changing material 20. Light source 43 may include one or more components, for example, light emitting diodes (LEDs), which may be placed in various locations within device 10. Light source 43 may additionally or alternatively be used as illumination source 42 (of Fig. 1), to illuminate the environment being imaged (outside of device 10). A separate illumination source 42 may be included for illumination material 20 and/or the in vivo environment. As local environmental changes, such as temperature changes, may cause color-changing material 20 to change color, an imager, such as 46, may acquire frames that capture the color of material 20 to determine its color at each selected point in time. For example, imager 46 may record or otherwise acquire an image of temperature sensitive color changing material 20 "n" times per second, thereby enabling the generation of data indicating the temperature in an in vivo environment for "n" intervals per second etc. In some embodiments, imager 46 may be a CMOS imager or any other suitable imager. Other light sources and/or imaging units may be used. Transmitter 41 may transmit at least the color changing data to data receiver unit 12.

[0029] In some embodiments of the present invention, device 10 includes at least one viewing window 21 through which the light from light source 43 and/or illumination source 42 (of Fig. 1) may illuminate inner portions of body lumen, such as the digestive system. Color-changing material 20, as described above, may be adhered or otherwise placed on the viewing window 21 in such a way that parts or all of material 20 remain transparent and preferably provide minimal or no viewing barriers or limitations to the imager's 46 view of the environment external to device 10. For example material 20 may be a spot or portion relative to the window 21. Thus, when device 10 is swallowed or otherwise enters into a body lumen, such as the

gastrointestinal tract, and proceeds to travel through the length of the lumen, the imager 46 may image the lumen wall and/or environment while simultaneously imaging the color-changing material 20. In this way, any change of color, due to an environmental change such as a change in temperature in the GI environment, for example, may be visible in the images acquired by imager 46 from, for example, the GI tract. Such embodiments may provide the viewer, for example, with images for each frame acquired, or for temperature data superimposed on each acquired image. Such an image, which may be a shaded image or temperature data etc., may be located in a portion of an image. In other embodiments suitable pH, pressure and/or other environment sensitive material may be used.

[0030] In some embodiments, a temperature-sensitive color-changing material 20 that may be used may be a thermotropic liquid crystal (TLC) paint or coating etc., such as are offered by Hallcrest, Inc. of Glenview, Illinois. Such TLCs, which may be cholesteric (comprised of sterol-derived chemicals), chiral nematic (comprised of non-sterol based chemicals) liquid crystals, a combination of the two, or any other forms or combinations of forms, may provide color changes in response to temperature changes. These color changes may be reversible or hysteretic. TLC may be used in various forms according to several embodiments of the present invention, including but not limited to paints, microencapsulated coatings and slurries, TLC coated polyester sheets, and unsealed films. Any other temperature-sensitive color-changing materials may be used, independently or in any combination.

[0031] In some embodiments of the present invention, temperature-sensitive color-changing material 20 may be sensitive to changes within a small range of temperatures, for fine, precise detection of temperature changes. For example, material 20 may be sensitive for small changes between, for example, 36 degrees Celsius and 39 degrees Celsius. In another embodiment, temperature-sensitive color-changing material 20 may be sensitive to changes within a larger range of temperatures, for example, from 30 degrees Celsius to 40 degrees Celsius, for more coarse determination of temperature and/or of temperature changes. Any range of sensitivities may be possible depending on the material used. For example, an in-vivo imaging device may be designed to determine temperature changes in the stomach, which typically range from 37-38 degrees Celsius, using a color changing material 20 that is highly sensitive to temperature change, such as a material that may change a